Informed Consent Form

OFFICIAL TITLE
Effectiveness of weekly and daily iron supplementation for the prevention of iron-deficiency anemia in infants. Impact on genomic stability.

NCT ID not yet assigned

03/01/2017

INFORMED CONSENT FORM

We are inviting you to participate in the research study named "**Effectiveness of weekly and daily iron supplementation for the prevention of iron-deficiency anemia in infants. Impact on genomic stability".**

Iron is an essential nutrient for children growth and development. When it is lacking, anemia may arise. Anemia can make your child tired, unwilling to play and to get sick more frequently and, if this is not corrected over time, he may have difficulties in school learning. In addition, the lack or excess of iron can damage and inside of the cell.

To avoid anemia, a preventive treatment every day with a drug (ferrous sulfate) is indicated to all children before the fourth month, except those who are only breast fed. Despite this recommendation, many children have anemia at 6 months of age.

The purpose of this study is to see if anemia can be reduced by the sixth month of life when iron supplementation is controlled. It will also be studied if the same results are obtained if the medication is given only once a week.

All children from birth who attend health checks and who have normal iron values can participate. When they attend the control of the third month, the children will be divided into five groups; if your child is breast fed, he/she may belong to groups 1, 2 or 3; on the other hand, if your child is breastfeeding and taking infant a bottle, he/she can belong to groups 4 or 5:

Group 1: children with exclusive breastfeeding to whom the iron supplement is not given
Group 2: children with exclusive breastfeeding, who will receive the preventive supplement with ferrous sulfate every day.
Group 3: children with exclusive breastfeeding, who will receive the preventive supplement with ferrous sulfate once a week.
Group 4: children with mixed feeding (breast and bottle) who will receive the preventive supplement with ferrous sulphate every day.
Group 5: children with mixed feeding (breast and bottle), who will receive the preventive supplement with ferrous sulfate once a week.

If you accept that your child participates in this study:

• A blood sample will be taken at 3 and 6 months of age to assess the iron status and the inside of the cell. The blood samples will be 3 ml each time (approximately one teaspoon) and the collection will be carried out by a professional with sterile and disposable material. The only risk is that your child may feel a little discomfort in the area of the puncture or will have a small bruise that will disappear in 2 or 3 days. This specimen will be analyzed in the Children's Hospital Laboratory of La Plata. In case of finding any alteration in the blood test, referral to a specialist will be suggested.

• You will be asked some questions about the characteristics of your home, your education and about the child's diet.

• You must commit to giving the medication in the manner indicated and complete an administration record that will be given to the pediatrician.

The benefits you will get from participating in this study will be:

• Know the nutritional iron status and if your child is anemic.

• Receive advice on feeding and nutrition.

• In the event that any alteration is detected, it will be informed and then referred to a specialist for its management.

• The medication (ferrous sulfate) and the studies your child will receive are free.

Your data will not be disclosed at any time, you will be assigned a code and only the main researcher of the study will know the relationship between the code and your personal data.

You can refuse to participate without this affecting your attention in the office; and you can withdraw at any time during the study, without this affecting your attention. You will not receive any payment with money in exchange for these studies.

For any questions you can call the researcher Ana Varea, at the number 0221-15541 1502.

This is a study financed by the Ministry of Health of the Province of Buenos Aires and has been approved by the Institutional Review Board. For any doubt or claim, you can contact the Board at the telephone number: 0221-4535901 int 1767.

Signature of mother/tutor	Signature of Researcher	Signature of a witness
Name of mother/tutor	Name of Researcher	Name of witness
ID:	ID:	ID:

Date and location…….